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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TON, THAIAN N

ART UNIT

PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/877,374

Applicant(s)

RAPP, JEFFREY C.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 and 9-29, drawn to methods for the production of an antibody by an avian cell, classified in class 435, subclass 69.1, 320.1 and 325+ and class 536, subclass 23.53, for example.
- II. Claims 1-29, drawn to methods for the production of an antibody by an avian cell wherein the avian cell is cultured *in vivo*, classified in class 800, subclass 4, for example.
- III. Claims 30-40, 51-56, 58, 60 and 61, drawn to methods for producing an avian which expresses a heterologous immunoglobulin polypeptide wherein the avian is produced by sperm-mediated transfer and transgenic avian, classified in class 800, subclass 4, 6, 8, 19, 21 for example.
- IV. Claims 30-38, 41-43, 51-55, 57, 60 and 61, drawn to methods for producing an avian which expresses a heterologous immunoglobulin polypeptide, wherein the avian is produced by nuclear transfer, and transgenic avian, classified in class 800, subclass 4, 6, 8, 19, 21 and 24, for example.
- V. Claims 44-45, 48, 51-55, 60 and 61, drawn to *in vivo* methods for producing transgenic avian that express a heterologous immunoglobulin polypeptide, comprising administering to an avian testis a gene delivery mixture comprising a viral vector having at least one heterologous polynucleotide encoding at least one heterologous immunoglobulin polypeptide, incorporating the heterologous polynucleotide into the genome of a spermatozoan cell to produce a genetically modified male gamete, mating the male avian with a female of the species to produce transgenic progeny, and transgenic avian, classified in class 800, subclass 8, 19, 21, for example.
- VI. Claims 46, 47, 49-55 and 59-61, drawn to an *in vitro* method for producing a transgenic avian comprising genetically modifying spermatozoan cells *in vitro* with a transgene, transferring the transfected spermatozoan cells into the testis of a recipient male, breeding the recipient male with a female to produce transgenic

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progeny, and transgenic avian, classified in class 800, subclass 8, 19, 21, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I and any of Inventions II-VI are mutually exclusive and independent. The methods for the production of an antibody by an avian cell of Invention I are not required for implementation of the methods for the production of an antibody by an avian cell wherein the avian cell is cultured *in vivo* of Invention II, the methods for producing an avian which expresses a heterologous immunoglobulin polypeptide wherein the avian is produced by sperm-mediated transfer and transgenic avian of Invention III, the methods for producing an avian which expresses a heterologous immunoglobulin polypeptide, wherein the avian is produced by nuclear transfer, and transgenic avian of Invention IV, the *in vivo* methods for producing transgenic avian of Invention V, and the *in vitro* method for producing a transgenic avian of Invention VI, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention II and any of Inventions III-VI are mutually exclusive and independent. The methods for the production of an antibody by an avian cell wherein the avian cell is cultured *in vivo* of Invention II are not required for the implementation of the methods for producing an avian which expresses a heterologous immunoglobulin polypeptide wherein the avian is produced by sperm-mediated transfer and transgenic avian of Invention III, the methods for producing an avian which expresses a heterologous immunoglobulin polypeptide, wherein the

avian is produced by nuclear transfer, and transgenic avian of Invention IV, the *in vivo* methods for producing transgenic avian of Invention V, and the *in vitro* method for producing a transgenic avian of Invention VI, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention III and any of Inventions IV-VI are mutually exclusive and independent. The methods for producing an avian which expresses a heterologous immunoglobulin polypeptide wherein the avian is produced by sperm-mediated transfer and transgenic avian of Invention III are not required for the implementation of the methods for producing an avian which expresses a heterologous immunoglobulin polypeptide, wherein the avian is produced by nuclear transfer, and transgenic avian of Invention IV, the *in vivo* methods for producing transgenic avian of Invention V, and the *in vitro* method for producing a transgenic avian of Invention VI, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Invention IV and either of Inventions V-VI are mutually exclusive and independent. The methods for producing an avian which expresses a heterologous immunoglobulin polypeptide, wherein the avian is produced by nuclear transfer, and transgenic avian of Invention IV is not required for the implementation of the *in vivo* methods for producing transgenic avian of Invention V, and the *in vitro* method for producing a transgenic avian of Invention VI, and vice versa.

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Furthermore, each of the methods requires a separate and materially different protocol.

Inventions V and VI are mutually exclusive and independent. The *in vivo* methods for producing transgenic avian of Invention V is not required for the implementation of the *in vitro* method for producing a transgenic avian of Invention VI, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

TNT

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